Janet Turk Wittes, Ph.D.

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Higher education

1970	Harvard University	Ph.D.	Statistics
1965	Harvard University	M.A.	Statistics
1964	Radcliffe College	A.B.	Mathematics

Employment

1991–	President, Statistics Collaborative, Inc.
1991–1992	Principal Research Scientist, New England Research Institute, Inc.
1989–1990	Biostatistician, Department of Veterans Affairs Medical Center, Cooperative Studies Program Coordinating Center, West Haven, CT
1983–1989	Chief, Biostatistics Research Branch, National Heart, Lung, and Blood Institute (NHLBI)
1974–1982	Assistant/Associate Professor, Department of Mathematical Sciences, Hunter College of the City University of New York
1973–1974	Adjunct Assistant Professor, Division of Epidemiology, Columbia University School of Public Health
1972–1973	Research Associate, Department of Statistics, The George Washington University
1970–1972	Research Associate, Department of Biostatistics, University of Pittsburgh School of Public Health

Honors and awards

Janet L. Norwood Award, For Outstanding Achievement by a Woman in the Statistical Sciences, The University of Alabama at Birmingham (2006)

Inaugural Fellow, Society for Clinical Trials (2006)

Fellow, American Association for the Advancement of Science (1994)

Fellow, American Statistical Association (1989)

Professional societies

American Association for the Advancement of Science (member since 1993)

American Statistical Association (member since 1965)

- Fellow, 1989
- Biometrics Section, Chair, 1992
- Search Committee for Executive Director, 1995
- Scientific Freedom and Human Rights Committee, 2012–

International Biometric Society (member since 1968)

- Treasurer, 1987–1990
- Finance Committee, 2000–2008
- Council Member, 2003–2008

International Biometric Society, Eastern North American Region (member since 1968)

- Regional Advisory Board, 1977–1980
- ENAR Program Chair for Joint Statistical Meetings, 1982
- Regional Committee, 1985–1990
- Short Course Committee, 1986
- Committee on Co-sponsorship of Professional Society Meetings, 1985
- New Initiatives Committee, 1987
- ENAR Representative on ASA Board, 1993
- Executive Committee, 1994–1996
- President, 1995

International Society for Clinical Biostatistics (member since 1995)

- Scientific Program Committee, 1996

International Statistical Institute

- Elected Member, 1996

Royal Statistical Society (member since 1995)

Society for Clinical Trials (member since 1983)

- Chairman, Nominating Committee, 1987
- Board of Directors, 1992–1994
- Chair, Program Committee, Annual Meeting 1994
- Publications Committee, 1993 and 2002–2004
- Executive Committee, 2000–2003
- President, 2001–2002
- Elected Inaugural Fellow, 2006

Board Service

Maryland Medical Research Institute, Board Member, 2004–2010

(b) (6)

Chair, Technology Committee, 2009–

Chair, Education Committee, 2011–

Editorial boards

Controlled Clinical Trials: Associate Editor, 1994–1998; Editor-in-Chief, 1993–1998; Editorial Advisory Board, 1999–2003

Cardiovascular Clinical Trials Forum: Advisory Board, 1996–2000

Statistics in Medicine: Associate Editor, 1981–1991

Trials: Associate Editor, 2008–2011

Clinical Trials: Editorial Advisory Board, 2003–

Pilot and Feasibility Studies: Editorial Board member, 2014–

Data monitoring and scientific advisory committees, current

Member, Designing Clinical Studies to Evaluate the Role of Nutrition and Diet in Heart Failure Management, NHLBI Working Group, 2013–

Member, WHO IVR/Global Malaria Programme Joint Technical Expert Group (JTEG), 2008–

Chair, Data and Safety Monitoring Committee, Age-related Eye Disease Study II (AREDS II), NEI, 2006–

Member, Clinical Trials Advisory Panel, National Institute on Aging, 2008–

Chair, Data and Safety Monitoring Committee, Multi-Center Uveitis Steroid Treatment (MUST) Trial, NEI, 2005–

Member, Data and Safety Monitoring Board, Resuscitation Outcomes Consortium, NHLBI, 2008–

Chair, C/SOAP DSMB, NICHD, 2010–

Member, FLAT-SUGAR DSMB, NIDDK, 2011–

Member or chair, various safety monitoring committees for trials sponsored by industry Studies in cardiovascular diseases, sepsis, cancer, critical care, vaccines, etc.

Data monitoring and scientific advisory committees, selected former (DSMB=Data and Safety Monitoring Board or Committee)

Chair, DSMB Atherothrombosis Intervention in Metabolic Syndrome with Low HDL/High Triglyceride and Impact on Global Health Outcomes (AIM-HIGH), NHLBI, 2006–2011

Chair, DSMB, Retinitis Pigmentosa Trial, National Eye Institute (NEI), 2002–2011

Chair, DSMB of the Folic Acid for Vascular Outcome in Transplantation Recipients Trial (FAVORIT), NIDDK, 2001–2009

Member, Diabetes Prevention Program (DPP) and Diabetes Prevention Program Outcomes Study (DPPOS), Data Safety Monitoring Boards, 1997–2008

Member, Committee on the Perspectives on the Role of Intermittent Preventive Treatment for Malaria in Infants, Institute of Medicine, 2007–2008

Member, Data Access and Publication Principles Group, Association of American Medical Colleges, 2005

Chair, Data and Safety Monitoring Board, Women's Health Initiative Clinical Trial, NIH, 1993–2004

Data Monitoring Committee, (b) (4) Trial, (b) (4) , 1982

Safety and Data Monitoring Committee for Phenobarbital Study, NINCDS, 1982–1988

Policy Advisory Board, Transfusion Safety Study (AIDS), NHLBI, 1984–1992

Cardiomyopathy Monitoring Committee, Division of Intramural Research, NIH, 1985–1988

DSMB for Antiepileptic Drug Development Studies, NINDS, 1986–1990

Safety and Efficacy Monitoring Board, (b) (4) Study, 1987–1990

Policy, Data and Safety Monitoring Board, Pediatric Pulmonary and Cardiovascular Complications of Vertically Transmitted HIV Infection (P2C2), NHLBI, 1989–2002

Data and Safety Monitoring Board, Postmenopausal Estrogen/Progestin Interventions Trial (PEPI), NHLBI, 1989–1995

Safety Monitoring Board, PiZZ Registry, NHLBI, 1989–1997

DSMB, Registry of Patients with Deficiency of Alpha$_1$-Antitrypsin, NHLBI, 1990–1996

DSMB, Trial to Reduce Alloimmunization to Platelets (TRAP), NHLBI, 1990–1995

DSMB, National Marrow Donor Program, 1990–1991

DSMB, Cholesterol Reduction in Seniors Program, NHLBI, 1991–1992

DSMB, Improving Intrauterine Contraception: (b) (4) , Inc., 1991–1995

Performance and Safety Monitoring Board, Randomized Indomethacin GMH/IVH Trial, NINDS, 1991–1992

Co-chair, Turner Syndrome DSMB, NIH, 1992–1993

DSMB, Arterial Disease Multifactorial Intervention Trial (ADMIT), NHLBI, 1992–1996

Policy Advisory Board, Cardiovascular Risk Factors in Young Adults, NHLBI, 1992–1998

DSMB, (b) (4) Trial, (b) (4) , 1993–1999

DSMB, VA Non-Q-wave Infarction Strategies in-Hospital, 1993–1997

Planning Group, Workshop on Meta-Analysis of Cholesterol-Lowering Trials, NHLBI, 1993–1994

Scientific Advisory Board, NIH-DC Infant Mortality Initiative, 1993–1994

DSMB, Mycosis Study Group Trials, 1994–2000

Advisory Panel, Study of Women's Health Across the Nation, National Institute on Aging, 1995–1996

AIDS and Related Research B Study Section, NIH, Member 1994–1997, Chair 1997–1998

Scientific Advisor, HDL Intervention Trial (VA-HIT), VA Cooperative Studies, 1989–2000

Chair, DSMB of the Age Related Eye Disease Study (AREDS), NEI, 1991–2000

Member, Executive Committee, The CONVINCE Trial, Sponsored by Searle, 1995–2002

DSMB, the ASCUS/LSIL Triage Study (ALTS), 1996–2001

Consultant, Anti-infective Drugs Advisory Committee, 1998–2000

Member, Medical Research Council of Canada, Grants Committee on Clinical Trials, 1998–2001; 2004–2006

Member, Circulatory System Devices Panel of the Medical Devices Advisory Committee, FDA, 1999–2003

Member, International Clinical Trials Subcommittee of the Scientific Advisory Committee, International AIDS Vaccine Initiative, 2000–2003

Advisor, FDA Statistical Advisors Orientation, sponsored by CBER, CDER, and CDRH, 2003

Member, Task Force on the NIH Women's Health Research Agenda for the 21st Century, 2003

Other professional activities

Air Pollution Working Group of the Health Research Council of NYC, 1974–1975

NIH Site Visit Teams and Technical Review Panels, 1976–1981, 1989

National Academy Science Committee on Odors from Stationary and Mobile Sources, 1978–1979

NIH Consensus Development Panel on the Management of Febrile Seizures, 1980

Working Group on Drug Development in Alzheimer's Disease, National Institute on Aging, 1987–1988

NIH Special Study Sections, Statistical Methodology, Member 1988–1991

Pulmonary AIDS Study, Division of Lung Diseases, NHLBI, Special consultant, 1989–1990

Systolic Hypertension in the Elderly Study, Division of Epidemiology and Clinical Applications, NHLBI Special consultant, 1989–1991

Working Session: Statistical Association Models, Wiesbaden, Germany, 1990 and 1992

Inclusion of Women in Clinical Trials, Institute of Medicine, Panelist, 1991

Institutional Review Board, Maryland Medical Research Institute, 1991–2007

National Marrow Donor Program, Consultant on statistical methods, 1991–1993

Working Group to Formulate a Request for Proposals for Condom Breakage Study, National Institute of Child Health and Human Development, 1991

AIDS and Related Programs NIH Study Section, 1993–1995; Chair 1996–1998

Board of Directors, Maryland Medical Research Institute, 1998–2007

NIH Technology Assessment Conference on Improving Medical Implant Performance through Retrieval Information: Challenges and Opportunities, 2000

Women's Hi-Tech Coalition, Washington, DC, 2003–2005

Planning Committee in the NIH Scientific Advances in Adaptive Clinical Trial Designs Workshop, Bethesda, MD, 2009

Data Monitoring Committees: Best Practices and Future Directions, Drug Information Association, Program Committee Member, 2012

Committee on Enhancing DSMBs, Multi-Regional Clinical Trials (MRCT) Center, Harvard University, 2012–

Invited courses and positions

Department of Physiology, Harvard Medical School: Micro-course in Statistics, Summer 1976

Faculty, 18th Summer Session in Biostatistics, Harvard School of Public Health, 1976

Memorial Sloan-Kettering Cancer Center, Department of Biostatistics, Visiting Investigator, 1977–1981

Department of Biostatistics & Epidemiology, Cleveland Clinic, Visiting Prof Pro Tempore, November 1990

Faculty, Foundation for Advanced Education in the Sciences, 1991–1992

Faculty, 7th and 8th International Symposium on Long-Term Clinical Trials, January 1991; September 1995

Faculty, Project LEAD Course on Biostatistics and Epidemiology, The National Breast Cancer Coalition Fund, October 1995

Faculty, NIH Summer Institute on Design and Conduct of Clinical Trials Involving Behavioral Interventions, Summer 2002, 2003, 2005, 2006

Faculty, Clinical Trial Essentials, Outcomes, and Issues for Eye Researchers, The Association for Research in Vision and Ophthalmology, National Autonomous University of Mexico, 2012

Grants and contracts (Principal Investigator)

Ascertainment Methods for Worker Populations—NIOSH Contract, 1980

The Power of the Mantel-Haenszel Test—PSC-CUNY Grant, 1980–1982

Data Coordinating Center, National Cooperative Inner City Asthma Study, National Institute of Allergy and Infectious Disease, 1990–1992

Software for Internal Pilot Studies for Clinical Trials, SBIR Grant Phase I, 1992–1993; Phase II, 1994–1996

NHLBI program responsibilities

Cardiovascular Risk Factors in Young Adults Study, Program Staff, 1983–1988
Data Management Committee, 1983–1985
Quality Control Committee, 1986–1988

Systolic Hypertension in the Elderly Program, Program Staff, 1983–1989
Recruitment Committee, 1983–1986
Adherence Committee, 1986–1989
Chair, Writing Committee, Data Analysis Chapter of Baseline Monograph, 1988–1989

Thrombolysis in Myocardial Infarction, Program Staff, 1983–1986

Workshop on Evaluation of Therapy, Organizing Committee, 1983

Atherosclerosis Risk in Communities Studies, Program Staff, 1984–1986
Member, Surveillance Committee, 1985–1986

Hypertension Intervention Pooling Project, Program Staff, 1984–1986

Working Group on Moderate Hypertension, Program Staff, 1984–1985

Workshop on Surrogate Endpoints, Organizing Committee, 1985

Alpha1-antitrypsin in PiZZ Patients Registry, Program Staff, 1986–1988
Member, Steering Committee, 1988–1989

Pediatric Pulmonary and Cardiovascular Complications of Vertically Transmitted Human Immunodeficiency Virus (HIV) Infection, Program Staff, 1986–1989

Post-CABG Trial, Program Staff, 1986–1989
Antiplatelet Working Group, 1987–1988

Pulmonary AIDS Study, Program Staff, 1986–1989
Chair, Data Analysis Committee, 1988
Special consultant to Program Staff, 1989

Working Group on Multiple Endpoints in Trials of Hypertension Prevention, 1987
Member, Subcommittee on Analytical Issues, 1987

Workshop on Cost and Efficiency of Clinical Trials, Organizing Committee, 1988

Invited presentations (selected)

Adaptation Not by Design – When, If Ever, Can We (Should We) Do It? DIA KOL Adaptive Design Webinar Series, 2015.

DMC report content/SAC contracts. DMC Think-Tank and Talk, McLean, VA, 2015.

How Should the Final Rule Affect DMCs? ICSA/Graybill Joint Conference, Fort Collins, CO, 2015.

Leadership Forum Panelists. ICSA/Graybill Joint Conference, Fort Collins, CO, 2015.

Introduction to IDMCs – A Training Course. Sponsored by The Harvard Clinical Trials Center, Bangkok, Thailand, 2015.

Update on the CTTI Safety Reporting Statistician Working Group. Society for Clinical Trials, Arlington, VA, 2015.

Adaptive designs: some cautionary notes. Johns Hopkins/FDA Course in Statistics, White Oak, MD, 2014.

Combining sample size adjustment with interim analysis: theory and operations. Society for Clinical Trials, Philadelphia, PA, 2014.

Considerations after stopping a trial early for overwhelming efficacy based on the primary outcome. 2014 ASA Biopharmaceutical Section FDA-Industry Statistics Workshop, Washington, DC, 2014.

Discussant: How to design personalized medicine trials investigating targeted therapies? 17th Global Cardio Vascular Clinical Trialists Workshop, Washington, DC, 2014.

Discussant: Regional differences in trials: do they exist? Can we detect/avoid them? Consequences for trial interpretation and regulatory approval. 17th Global Cardio Vascular Clinical Trialists Workshop, Washington, DC, 2014.

Discussant: Resource considerations and implementation barriers. Public Workshop: Strategies for responsible sharing of clinical trial data, Institute of Medicine, Washington, DC, 2014.

Discussant: Safety issues. Biostatistics and FDA regulation: the convergence of science and law, Food and Drug Law Institute, Cambridge, MA, 2014.

Moderator: Can we handle the truth: roundtable discussion. Biostatistics and FDA regulation: the convergence of science and law, Food and Drug Law Institute, Cambridge, MA, 2014.

On data for DMCs: Clean or speedy? Complete or limited? Society for Clinical Trials Webinar, 2014.

On supervising males (if you are a female statistician). Conference on Women in Statistics, Cary, NC, 2014.

Preconference Workshop: Independent Data Monitoring Committees recommendations for trials with an adaptive design: what, how, and to whom? Society for Clinical Trials, Philadelphia, PA, 2014.

Some thoughts about composite and other complicated outcomes. Conference on Innovations in the Science and Practice of Clinical Trials, Rockville, MD, 2014.

Adaptive clinical trials. Heart Failure and Nutrition Workshop, NHLBI, Bethesda, MD, 2013.

Data sharing from clinical trials. QSPI, Silver Spring, MD, 2013.

DMCs and the new Final Rule: how should we respond? Joint Statistical Meetings, Montreal, Canada, 2013.

Getting a seat at the table. Georgetown Biostatistics Department, Washington, DC, 2013.

Preconference Workshop: So you are invited to a DSMB: Now what? Society for Clinical Trials, Boston, MA, 2013.

Preconference Workshop: DSMBs for multiregional clinical trials, Harvard Multicenter Regional Trial Committee, Boston, MA, 2013

Moderator: Alternatives to time-to-first event. 15th Cardiovascular Clinical Trialists Workshop (CVCT), Paris, France, 2012.

How and how long should we look for long term safety of drugs that we prescribe for life? 15th Cardiovascular Clinical Trialists Workshop (CVCT), Paris, France, 2012.

Discussant: To adjudicate or not to adjudicate. 15th Cardiovascular Clinical Trialists Workshop (CVCT), Paris, France, 2012.

Data Safety Monitoring Boards: Planning and Execution. Short course at Biopharmaceutical Applied Statistics Symposium XIX, Savannah, GA, 2012.

Trials of safety: sample sizes and informed consent. ASA Biopharmaceutical Section FDA-Industry Statistics Workshop, Washington, DC, 2012.

Monitoring adaptive clinical trials. Joint Statistical Meeting (JSM), San Diego, CA, 2012.

History of the NHLBI Biostatistics Branch and its role in the early development of clinical trials. Symposium Celebrating 30 Years at the University of Wisconsin, Madison, WI, 2012.

Adaptive designs: are they practical and efficient? 3rd Sensible Guidelines for the Conduct of Clinical Trials, Ontario, 2012.

Panel member: Emerging statistical issues in biomarker validation for clinical trials. University of Pennsylvania Annual Conference on Statistical Issues in Clinical Trials, Philadelphia, PA, 2012.

Statistics and public policy. American Statistical Association, Alexandria, VA, 2012.

Dose selection for phase III trials. 14th CardioVascular Clinical Trialists (CVCT) Workshop, Paris, France, 2011.

Some cautionary notes on adaptive designs. Johns Hopkins Bloomberg School of Public Health, Center for Clinical Trials Visiting Scholar Seminar Series, Baltimore, MD, 2011.

Data Monitoring Committee experiences in multi-regional clinical trials. 5th Annual FDA/DIA Statistics Forum, Bethesda, MD, 2011.

Emerging/adaptive designs and other statistical issues with pilot studies. UCSF Symposium on Pilot Studies, San Francisco, CA, 2011.

Analysis of randomized clinical trials of orphan diseases. Fourth Annual Bayesian Biostatistics Conference, Houston, TX, 2011.

Panel member: Definition, adjudication and harmonization of endpoints. DIA/FDA Best Practices for Regulatory Information Synthesis of Randomized Controlled Trials for Product Safety Evaluation, Bethesda, MD, 2011.

Data Monitoring in Practice: Making Your Data Monitoring Committee Effective. American Statistical Association Biopharmaceutical Section Webinar Series, 2010.

Safety monitoring. Forum on Drug Discovery, Development, and Translation, Washington, DC, 2010.

Responder Analysis 1 (Bad) and 2 (Good). FDA/Industry Statistics Workshop, Washington, DC, 2010.

Micro-macro, FDA-EMA: On developing diabetes drugs. Drug Information Association meeting, Washington, DC, 2010.

The multi-regional clinical trial project (MRCT) enhancing respect for research participants, safety, and fairness in multi-regional clinical trials, Drug Information Association meeting, Washington, DC, 2010.

Statistics for trials: How big should my study be? Key judgments, components, and approaches to sample size and other relevant aspects of study design. Statistics: How do I analyze the results of my RCT? Statistics for observational studies: Analytical approaches for observational studies. Medical Research Council: International course in health research methodology, Zevenwacht, South Africa, 2010.

Issues with unplanned sample size recalculation in randomized clinical trials. NIH Scientific Advances in Adaptive Clinical Trial Designs Workshop, Bethesda, MD, 2009.

Short-course Workshop (with Thomas Fleming): Data Monitoring Committees: Statistical and practical issues. FDA/ASA workshop, Washington, DC, 2009.

Non-inferiority in orphan diseases: can we improve upon existing therapies? International Biometric Society, Eastern North American Region (ENAR), San Antonio, TX, 2009.

Round table leader: Indemnification for consultants and DSMB members: who protects whom? Joint Statistical Meeting (JSM), Washington, DC, 2009.

Insinuating ourselves early: how statisticians can become active participants in pharmaceutical development teams. International Chinese Statistical Association, Applied Statistics Symposium, San Francisco, CA, 2009.

Short-course FDA workshop on "Data and Safety Monitoring in Clinical Trials". Food and Drug Administration, Rockville, MD, 2009.

Why do so many people ignore missing data in randomized clinical trials? Merck-Temple Conference, Plymouth, PA, 2008.

Why are we so often not at the table (and what we must do to get there)? 10th Anniversary Johnson & Johnson Pharma Statistics Meeting, Raritan, NJ, 2008.

Discussant: Effective interactions of the DMC, Steering Committee, and Sponsor in a long-term prevention trial. Joint Statistical Meeting (JSM), Denver, CO, 2008.

Discussant: Perspectives on adaptive designs. 44th Annual Drug Information Association Meeting (DIA), Boston, MA, 2008.

Short-course Preconference Workshop (with Scott Evans): Data Safety Monitoring Committees. 29th Annual Meeting Society for Clinical Trials, St. Louis, MO, 2008.

Safety, Can you paradigm? A statistical lament (keynote address). Graybill Conference VII, Denver, CO, 2008.

Panel Discussion: The future of the education of clinical trials statisticians: What changes are needed? Graybill Conference VII, Denver, CO, 2008.

Schumi J, Rosenberg Z, Dickinson S, and Wittes, J. Conditional power considerations in the design of a Phase 3 microbicide trial in Africa. International Biometrics Society, Eastern North American Region (ENAR), 2008.

Now *You* Monitor the Women's Health Initiative Hormone Trials (keynote address). Population Health Research Institute Retreat, Hamilton, Ontario, 2007.

Practical issues in dealing with the FDA: DSMBs - Keys to setting one up and its operations. The Harvard Clinical Trials Workshop, Boston, MA, 2007.

Women's Health Initiative Estrogen Replacement Trial. NIH STEP Conference: Someone to Watch Over Me: Data Safety Monitoring of NIH-supported clinical trials, 2007.

Discussant: DSMB Responsibilities. 10th CardioVascular Clinical Trialists Workshop (CVCT), Paris, France, 2007.

Identifying harms in randomized clinical trials: Can we do better?
Boston University, Biostatistics Visiting Professor Day Clinical Trials Seminar, 2007.

Some statistical approaches for identifying harms in randomized clinical trials: 4th Conference of the Eastern Mediterranean Region of the International Biometric Society (EMR-IBS), Eilat, Israel, 2007.

Adaptive designs in cardiovascular trials: 9th CardioVascular Clinical Trialists Workshop (CVCT), Paris, France, 2006.

Discussant: Unconventional endpoints pros and cons. 9th CardioVascular Clinical Trialists Workshop (CVCT), Paris, France, 2006.

Looking backwards and forwards: Some methodological battles in randomized clinical trials. University of Pittsburgh, 2006.

Censoring, multiplicity, and over-classification: Some statistical approaches for failing to identify harms in randomized clinical trials. The University of Alabama at Birmingham, 2006.

Revenge of the α–police: Thoughts on multiplicity and safety. NIAID/BRB Seminar, 2006.

DSMBs: Statistical dos and don'ts. 42nd Annual Drug Information Association (DIA) Meeting, Philadelphia, PA, 2006.

FDA's guidelines on independent monitoring of trials: Are they helping and can they be improved? Harvard Department of Biostatistics, Schering-Plough Workshop, Boston, MA, 2006.

Discussant: A new approach to the use of historical controls for evaluating new drugs: A case study. 27th Annual Society for Clinical Trials Meeting (SCT), Orlando, FL, 2006.

Clinical considerations in the development and review of severe sepsis biologic and drug products. Drug Information Association Statistical Methodologies in the Biopharmaceutical Sciences Workshop, Washington, DC, 2006.

Interim monitoring for efficacy in randomized clinical trials. FDA Center for Drug Evaluation and Research (CDER) Biostatistics Seminar, Washington, DC, 2006.

A view from an outside statistician: Some thoughts in two parts. FDA CDER Biostatistics Seminar, Washington, DC, 2006.

Statistical approaches to hiding safety signals. Harvard Department of Biostatistics, Schering-Plough Workshop, Boston, MA, 2005.

Panel discussion on safety. Harvard Department of Biostatistics, Schering-Plough Workshop, Boston, MA, 2005.

How many statisticians does it take to do a t-test? – Conflicts of statistical roles in industry-sponsored clinical trials – Roundtable discussion leader. International Biometric Society, Eastern North American Region (ENAR), Austin, TX, 2005.

Statistical concerns under the Federal Advisory Committee Act (FACA) – Panelist. International Biometric Society, Eastern North American Region (ENAR), Austin, TX, 2005.

Basic principles of clinical trial design. Considering Usual Medical Care in Clinical Trials Design: Scientific and Ethical Issues. NIH Program on Clinical Research Policy Analysis and Coordination, Bethesda, MD, 2005.

Methods for incorporating flexibility in clinical trials. Biopharmaceutical Applied Statistics Symposium (BASS XI), Savannah, GA, 2004.

Keynote address: Why do they hate us? A door to the inner sanctum. Biopharmaceutical Applied Statistics Symposium (BASS XI), Savannah, GA, 2004.

Why specify best practices for DSMBs? Joint Statistical Meeting (JSM), Toronto, Canada, 2004.

Making independence work. Society for Clinical Trials, New Orleans, LA, 2004.

Discussant: FDA Bayesian Methods in Clinical Trials, Bethesda, MD, 2004.

DMCs for multinational trials: Plus la même chose? DIA Workshop on Clinical Trial Data Monitoring Committees, Bethesda, MD, 2003.

Elixer of youth? Hormone replacement therapy. The Institute for Learning in Retirement, Washington, DC, 2003.

Issues in randomized clinical trials involving behavioral interventions: Analytic methods. NIH Natcher Conference Center, 2003.

Confidentiality documents for DSMBs. Duke Clinical Research Institute: Conference and Controversies in the Operation of Clinical Trials Monitoring Committees, 2003.

What to expect at your first advisory meeting. FDA Statistical Orientation, 2003.

How to put together a Phase III DSMB and what it is like being on a Phase III DSMB. Data and Safety Monitoring Plans: The Basics for Clinical Research, Tufts-New England Medical Center, General Clinical Research Center, 2002.

Sample size: A window into designs of clinical trials. Center for Drug Development Science, Georgetown University Medical School International Fellowship Program Curriculum, 2002.

Data monitoring. Seminar sponsored by the Child Neurology Society, 2002.

Safety monitoring: The role of statistics. University of Virginia General Clinical Research Center Symposium, 2002.

Bending the rules: Some approaches to statistical flexibility in clinical trials. Harvard Schering-Plough workshop on emerging strategies in designing and monitoring clinical trials. Harvard University Department of Biostatistics, 2002.

Controversies in medicine: Clinical trials on trial. Seminar sponsored by Staff Training in Extramural Programs (STEP) Committee, National Institutes of Health, 2001.

Sex and gender analysis in health research. Seminar and panel discussion sponsored by the Office of Research on Women's Health, National Institutes of Health, 2000.

Sample size issues in clinical trials: Modification of sample size during a trial. Ninth International Symposium on Long-term Clinical Trials–Advanced Issues in the Design and Conduct of Randomized Clinical Trials, 2000.

Views from a statistical consultant. 23rd Annual Midwest Biopharmaceutical Statistics Workshop, 2000.

Some practical experiences with sample size recalculation. 23rd Annual Midwest Biopharmaceutical Statistics Workshop, 2000.

Stopping trials for futility: The use of conditional power. Oberwolfach Conference on Medical Statistics, Current Developments in Statistical Methodology for Clinical Trials and Statistical Challenges of Molecular Medicine, 2000.

Women, smokers, and Libras: When do we believe subgroups? 22nd Annual Midwest Biopharmaceutical Statistics Workshop, 1999.

When and how to report on studies indicating no benefit or harm. 20th Annual Meeting of the Society for Clinical Trials, 1999.

Looking at safety in clinical trials: during and after. Symposium Program, NJ Chap Am Stat Assn, 1999.

Effective use of DSMBs in Phase III clinical trials. Georgetown Center for Drug Development Science, 1999.

Contrasting characteristics of clinical trials sponsored by government versus industry. 20th Annual Meeting of the Society for Clinical Trials, 1999.

Effective use of data safety monitoring boards. Georgetown Center for Drug Development Science, 1998.

Disentangling competing risks. The Christian R. Klimt Joint Seminar Series on Clinical Trials, 1998.

Data and Safety Monitoring Boards: What should they see? Center for Drug Evaluation and Research, Food and Drug Administration, 1998.

Data and Safety Monitoring Boards: Design and methods of clinical trials. University of Alabama at Birmingham School of Medicine Clinical Trials Symposium, 1998.

Peer review, process problems, and ethical dilemmas facing journal editors, or what my mother should have told me about being a journal editor. 10th Annual Optometric Clinical Research Symposium, American Academy of Optometry, 1996.

DSMBs: Issues and controversies. Society for Clinical Trials Annual Meeting, 1996.

Questions please? Joint Statistical Meetings, 1995.

Meta-analysis. National Breast Cancer Coalition, Project LEAD, 1995.

How I learned to live without malpractice insurance. Virginia Tech, Department of Statistics, 1995.

Changing trials midstream. Nathan Kline Institute of Psychiatry, 1995; Department of Biostatistics, Johns Hopkins School of Public Health, 1995.

Can it work? Does it work? Differing expectations for clinical trials. American Association for the Advancement of Science Meeting, 1995.

Women and minorities in clinical trials. NIH Epidemiology Committee Seminar, 1994.

Who should be included in clinical trials? Teaching Day, American College of Neuropsychiatry, 1994.

Subgroups in sepsis trials. IBS Conference on Randomized Clinical Trials in Sepsis, 1994.

Subgroups in clinical trials - A view from South of the Border. Department of Medicine, McMaster University, Hamilton, Ontario, 1994.

Meta-analysis: An ambivalent overview. The Cochrane Collaborative, 1994.

Issues in sample size calculations. Department of Biostatistics, U Iowa School of Public Health, 1994.

Internal pilot studies. Wyeth Laboratories, 1994.

Interim analysis: The relationship between study investigators, monitoring panels, and trial sponsors. National Multiple Sclerosis Workshop, 1994.

How institutions will need to adapt to implement new rules on research populations in clinical research. Clinical Cocaine Seminar, NIMH, 1994.

Elements of the design and conduct of single-and multi-site clinical trials. International Association for Dental Research, 1994.

Censoring by death in randomized clinical trials. FDA, 1994.

An overview of cholesterol-lowering trials. NHBLI Workshop on Cholesterol Lowering Trials, 1994.

Timing of internal pilot studies. ENAR Spring Meetings, 1993.

Thoughts of an accidental entrepreneur. Can a statistician earn a living on her own? Joint Statistical Meetings, 1993.

The Physician's Health Study. Johns Hopkins Course on Ethics and Politics of Clinical Trials, 1993.

Internal pilot studies in clinical trials. Harvard-Schering-Plough Workshop on Clinical Trials, 1993.

Internal pilot studies in clinical trials. Conn Chap Am Stat Assn, 1993.

Intention-to-treat in clinical trials. Conference of NASPE, 1993.

Compliance in clinical trials of chronic disease: A statistical perspective. NIH Reunion Task Force Conference on the Science of Compliance, 1993.

The data monitoring board in clinical trials. NHLBI-VA Digitalis Study Group, 1992.

Subgroup analyses in clinical trials. Workshop of VA Cooperative Group Statisticians, 1992.

Sample size re-estimation in clinical trials. Drug Information Association, 1992.

Inclusion of women in clinical trials. Johns Hopkins School of Public Health, 1992.

Fitting retrospective data into prospective studies. DIA Workshop "Epidemiology and the Evaluation of Medical Interventions", 1992.

Behind closed doors: The purpose of data monitoring in randomized clinical trials. Workshop on Practical Issues in Data Monitoring of Clinical Trials, NIH, 1992.

On entry criteria for clinical trials. University of Minnesota School of Public Health, 1991.

Internal pilot studies and expediting drug development. Midwest Biopharm Stat Workshop, 1991.

Behind closed doors: The data monitoring committee in clinical trials. Conference on "Moving Clinical Trials into the Twenty-First Century", Del Chap Am Stat Assn, 1991.

Statistical issues in the design of clinical studies. Workshop on Intervention in Idiopathic Pulmonary Fibrosis, NHLBI, 1990.

Issues in the design of SHEP. Preventive Cardiology Rounds, Yale School of Medicine, 1990.

Estimating normal ranges in α1-antitrypsin deficiency: A statistical model of an upregulatable gene. Am Public Health Assn, 1990; Cleveland Clinic Research Foundation, 1990; Washington Statistical Society, 1990.

Stochastic curtailing in clinical trials. Mount Sinai School of Medicine, 1989.

Internal pilot studies in clinical trials. Columbia University School of Medicine, 1989.

Eyes, teeth, and bypass grafts: Evaluating the effect of therapy in treatments with correlated binomial outcomes. Yale Biostatistics and Epidemiology Seminar, 1989.

On the power of the Mantel-Haenszel test. Washington Statistical Society, 1987.

On surrogate endpoints in cardiovascular clinical trials. ENAR Spring Meetings, 1987.

Relative advantages and disadvantages of using observational data bases to evaluate the effects of treatments. Plenary Session, Society of Clinical Trials, 1987.

Panel member: Evaluation of medical therapies. 11th Annual Symposium on Computer Applications in Medical Care, 1987.

Capture-recapture models in epidemiology: The problem of bogus data. Conference on "Modeling Discrete Data", Del Chap Am Stat Assn, 1987.

The statistician as data monitor in clinical trials. Baruch College, 1986.

The design & analysis of clinical trials – A view from the other side. NJ Am Stat Assn, 1985.

Statistical perspectives on medical screening. Joint Statistical Meetings, 1983.

Estimating the size of worker populations. Joint Statistical Meetings, 1983.

An overview of capture-recapture methods. SRI-IBM, 1982, 1983.

Capture-recapture methods for estimating the total number of workers exposed to specific risks and hazards. Rockefeller University Comparative Toxicology Seminar, 1981.

The Mantel-Haenszel test: Power and design. CALG-B, 1980.

Some problems in ascertainment methodology. NIOSH, 1980.

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